REMARKS

Claims 1-55 are pending. Claim 1 has been amended to incorporate the preamble "an immediate release solid dosage form" into the body of the claim. Claim 16 has been amended to incorporate the preamble "an immediate release tablet" into the body of the claim. Support for these claim amendments can be found in original claims 1 and 16, respectively, and in the specification at, for example, page 28, line 31 to page 29, line 2.

The claim rejections under 35 U.S.C. § 103(a) for obviousness

Claims 1-55 have been rejected as obvious over U.S. Patent Publication No. 2001/0005512 in view of Remingtons' Pharmaceutical Sciences (1990) ("Remington") or U.S. Patent No. 6,419,953 in view of Remington.

According to the Examiner, the '512 application discloses: (1) pharmaceutical compositions comprising valproate compounds such as divalproex sodium as the active agent, (2) tablets including the active agent and hydroxypropyl cellulose, (3) fillers including microcrystalline cellulose and lactose, (4) lubricants including magnesium stearate, and (5) the treatment of conditions such as epilepsy and bipolar disorder. The Examiner contends that optimizing the amount of excipient was "within the scope of a skilled artisan." Office Action, page 3.

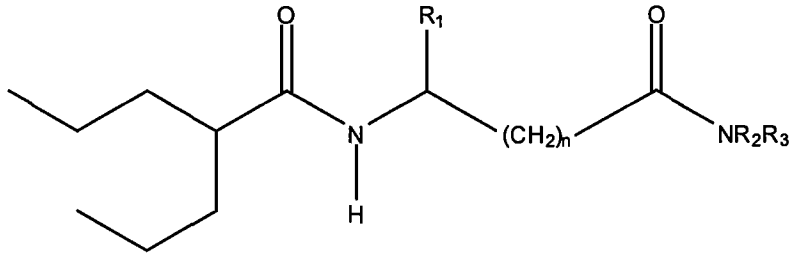
According to the Examiner, the '953 patent discloses a controlled release composition comprising valproic acid or its salts, hydroxypropyl methylcellulose, and excipients (e.g., magnesium stearate, lactose, microcrystalline cellulose), which are formed into tablets by compression. The Examiner acknowledges that '512 and '953 do not disclose a disintegrant.

Remington discloses the use of disintegrants to "allow the quick break up of the tablet for its rapid dissolution." Office Action, page 5. The Examiner contends that "a skilled artisan would have employed an appropriate amount of a disintegrant" in the composition of the '512 application or '953 patent to arrive at "the desired release rate." *Id.*

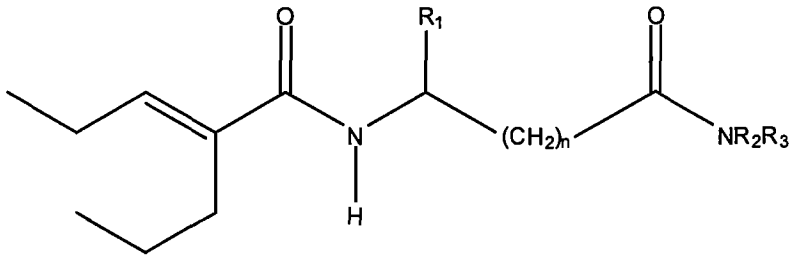
The Examiner states that the preamble of the instant claims (i.e., immediate release dosage form or tablet) "does not add any patentable weight." Office Action, pages 3-4.

Independent claims 1 and 16 have been amended to incorporate the preamble into the body of the claims and to thereby clarify that the claimed dosage forms are immediate release formulations.

The '512 application discloses a controlled release formulation for once-a-day administration. *See,* '512, abstract and throughout the '512 specification. The '953 patent discloses a once-a-day, controlled release formulation. *See,* '953, abstract, col. 2, l.. 46-47, and throughout the '953 specification. *See also,* Office Action, p. 3. Remington does not disclose immediate release valproic acid formulations. Thus, the instant claims are non-obvious because no combination of references discloses or suggests an immediate release dosage form comprising valproic sodium acid, a pharmaceutically acceptable salt or ester of valproic acid, divalproex sodium, valpromide or a compound having the structure:



or



wherein R_1, R_2, and R_3 are independently the same or different and are hydrogen, a C_1-C_6 alkyl group, an aralkyl group, or an aryl group, and n is an integer which is greater than or equal to 0 and less than or equal to 3.

Further, none of the prior art references can be properly modified to result in the instantly claimed immediate release dosage form. The '512 application and the '953 patent are directed to once-a-day formulations. The Examiner proposes modifying the '512 or '953 prior art to include a disintegrant (i.e., a substance added to a tablet to facilitate its breakup after administration to allow for *rapid dissolution*). This is an improper combination of references because if would destroy the controlled release properties of the '512 and '953 compositions. *See,* MPEP 2143.01 ("If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.").

Thus, this rejection should be withdrawn because no combination of references discloses or suggests an immediate release valproic acid solid dosage form, and no prior art can be properly modified to include the claimed active agents and a disintegrant.

The Information Disclosure Statement filed July 2, 2004

According to the Examiner, the Information Disclosure Statement (IDS) filed on July 2, 2004 did not properly list the references on the Patent Office's form PTO-1449. A compliant form PTO SB/08 accompanies this response.

Conclusion

No new matter has been added by these amendments. In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

Dated: August 10, 2007

By _____

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